

## § 872.3740

movements to aid in construction of restorative and prosthetic dental devices. A marking pen is attached to the lower jaw component of the device and, as the patient's mouth opens, the pen records on graph paper the angle between the upper and the lower jaw.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 66 FR 38798, July 25, 2001]

## § 872.3740 Retentive and splinting pin.

(a) *Identification*. A retentive and splinting pin is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be placed permanently in a tooth to provide retention and stabilization for a restoration, such as a crown, or to join two or more teeth together.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9

[52 FR 30097, Aug. 12, 1987, as amended at 60 FR 38900, July 28, 1995; 66 FR 38798, July 25, 2001]

## § 872.3750 Bracket adhesive resin and tooth conditioner.

(a) *Identification*. A bracket adhesive resin and tooth conditioner is a device composed of an adhesive compound, such as polymethylmethacrylate, intended to cement an orthodontic bracket to a tooth surface.

(b) *Classification*. Class II.

## § 872.3760 Denture relining, repairing, or rebasing resin.

(a) *Identification*. A denture relining, repairing, or rebasing resin is a device composed of materials such as methylmethacrylate, intended to re-

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line a denture surface that contacts tissue, to repair a fractured denture, or to form a new denture base. This device is not available for over-the-counter (OTC) use.

(b) *Classification*. Class II.

## § 872.3765 Pit and fissure sealant and conditioner.

(a) *Identification*. A pit and fissure sealant and conditioner is a device composed of resin, such as polymethylmethacrylate, intended for use primarily in young children to seal pit and fissure depressions (faults in the enamel) in the biting surfaces of teeth to prevent cavities.

(b) *Classification*. Class II.

## § 872.3770 Temporary crown and bridge resin.

(a) *Identification*. A temporary crown and bridge resin is a device composed of a material, such as polymethylmethacrylate, intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated.

(b) *Classification*. Class II.

## § 872.3810 Root canal post.

(a) *Identification*. A root canal post is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be cemented into the root canal of a tooth to stabilize and support a restoration.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 60 FR 38900, July 28, 1995; 66 FR 38798, July 25, 2001]

## § 872.3820 Root canal filling resin.

(a) *Identification*. A root canal filling resin is a device composed of material, such as methylmethacrylate, intended for use during endodontic therapy to fill the root canal of a tooth.

(b) *Classification*. (1) Class II if chloroform is not used as an ingredient in the device.

(2) Class III if chloroform is used as an ingredient in the device.

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(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any root canal filling resin described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a root canal filling resin described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other root canal filling resin shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 50707, Sept. 27, 1996]

### §872.3830 Endodontic paper point.

(a) *Identification.* An endodontic paper point is a device made of paper intended for use during endodontic therapy to dry, or apply medication to, the root canal of a tooth.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989; 66 FR 38798, July 25, 2001]

### §872.3840 Endodontic silver point.

(a) *Identification.* An endodontic silver point is a device made of silver intended for use during endodontic therapy to fill permanently the root canal of a tooth.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989; 66 FR 38798, July 25, 2001]

### §872.3850 Gutta percha.

(a) *Identification.* Gutta percha is a device made from coagulated sap of certain tropical trees intended to fill the root canal of a tooth. The gutta percha is softened by heat and inserted

into the root canal, where it hardens as it cools.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989; 66 FR 38798, July 25, 2001]

### §872.3890 Endodontic stabilizing splint.

(a) *Identification.* An endodontic stabilizing splint is a device made of a material, such as titanium, intended to be inserted through the root canal into the upper or lower jaw bone to stabilize a tooth.

(b) *Classification.* Class II.

### §872.3900 Posterior artificial tooth with a metal insert.

(a) *Identification.* A posterior artificial tooth with a metal insert is a porcelain device with an insert made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to replace a natural tooth. The device is attached to surrounding teeth by a bridge and is intended to provide both an improvement in appearance and functional occlusion (bite).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38798, July 25, 2001]

### §872.3910 Backing and facing for an artificial tooth.

(a) *Identification.* A backing and facing for an artificial tooth is a device intended for use in fabrication of a fixed or removable dental appliance, such as a crown or bridge. The backing, which is made of gold, is attached to the dental appliance and supports the tooth-colored facing, which is made of porcelain or plastic.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in